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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,242	03/21/2001	Robert Haselbeck	ELITRA.011A	7191

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EXAMINER

GIBBS, TERRA C

ART UNIT PAPER NUMBER

1635

DATE MAILED: 06/03/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/815,242

Applicant(s)

HASELBECK ET AL.

Examiner

Terra C. Gibbs

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-100 is/are pending in the application.
- 4a) Of the above claim(s) 1-11, 13-30 and 32-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 12, 31, and 44-100 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to the Amendment filed March 4, 2003, in Paper No. 14.

Claims 1-100 are pending in the instant application.

Claims 12 and 31 have been amended. New claim 100 is acknowledged. Claims 1-11, 13-30, and 32-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 14.

Claims 12, 31, and 44-100 have been examined to the extent they read on the elected subject matter.

Election/Restrictions

Applicant's election of Group VII (claims 12 and 31) without traverse and election of SEQ ID NO: 12600 with traverse, filed October 28, 2002 in Paper No. 12 is acknowledged. Additionally, Applicant's election of SEQ ID NO: 1463 with traverse, filed March 4, 2003 in Paper No. 14 is acknowledged. The traversal is on the ground(s) that the current law permits the examination of more than one sequence when each of the sequences is embraced by a generic linking claim and a search of each of the sequences recited in the elected claim set would not represent an undue burden on the Patent and Trademark Office. Applicants argue that although the nucleic acids and polypeptides recited in the methods of the instant invention are patentably distinct, the Court of Appeals for the Federal Circuit has recognized that Applicant is entitled to the examination of a generic claim encompassing a number of polynucleotides or polypeptides when the application provides a representative number of related sequences which fall within the

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scope of the generic claim. For support, Applicants cite *The Regents of the Univ. of Calif. V. Eli Lilly & Co.*, 119 F.3d 1559, 1569 (Fed. Cir. 1997). Applicants further argue that the instant invention provides the sequences of several antisense nucleic acids which are complementary to the *Staphylococcus aureus* and *Enterococcus faecalis yphC* genes, the sequence of the *yphC* gene from several organisms and the sequences of the YphC polypeptides from several organisms. Applicants point out that the instant specification provides the antisense nucleic acids of SEQ ID NOs: 1390, 1463, 1845, 2782, 3283, which are complementary to the *Staphylococcus aureus yphC* gene, and the antisense nucleic acid of SEQ ID NO: 521, which is complementary to the *Enterococcus faecalis yphC* gene of SEQ ID NO: 6592, as well as the *yphC* gene from several different organisms having SEQ ID NOs: 3966, 6154, 6872, 7273, 7857, 8502, 9420, and 9605; and the YphC polypeptides from several different organisms of SEQ ID NOs. 5021, 5283, 10251, 10689, 10969, 11370, 11955, 12600, 13518 and 13703. Applicants point out the substantial structural relationship and biological interrelationship between the *yphC* antisense nucleic acids, *yphC* coding sequences and YphC polypeptide sequences of the instant invention.

Applicant's arguments have been fully considered but are not found persuasive. See 35 U.S.C. 121 and 37 C.F.R. 1.141 where the Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a single application. Under this policy, up to 10 of independent and distinct nucleotide sequences will be examined in a single application (see MPEP 803.04 and 2434).

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In view of Applicant's Amendments, the following additional restriction election is required:

A. As Applicants have pointed out, the pending claims include sequences which relate to one or more of the following: (1) antisense nucleic acids complementary to at least a portion of the *yphC* gene; (2) the *yphC* gene from different organisms; and (3) YphC polypeptides from different organisms. Although the antisense nucleic acid sequences claimed each target the same gene and the polypeptide sequences encode the same gene, the instant antisense nucleic acid sequences are considered to be unrelated, since each sequence claimed is structurally and functionally independent and distinct for the following reasons: each sequence has a unique nucleotide sequence, each nucleic acid sequence targets a different and specific region of the *yphC* gene, and each antisense nucleic acid, upon binding to the *yphC* gene, functionally modulates (increases or decreases) the expression of the gene and to varying degree (per applicant's Table VIIA in the specification). Furthermore, a search of more than one (1) of the *yphC* antisense sequences, *yphC* target sequences, and polypeptide sequences presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed sequences. In view of the foregoing, one (1) *yphC* antisense sequence, one (1) *yphC* target gene and one (1) YphC polypeptides is considered to be a reasonable number of sequences for examination.

Accordingly, applicants are required to elect one (1) *yphC* antisense sequence, one (1) *yphC* target gene and one (1) YphC polypeptide to be examined with the elected invention, which invention is restricted thereof. It is noted that this requirement regards pending claims 12,

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31, and 44-100. It is further noted that the elected *yphC* antisense, *yphC* target gene and YphC polypeptide sequences must all correspond with each other.

B. Claims 48, 50, 88 and 90 are generic to a plurality of disclosed patentably distinct species. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. It is noted that the elected species from claims 48 and 88 must correspond to the elected species from claims 50 and 90, respectively.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

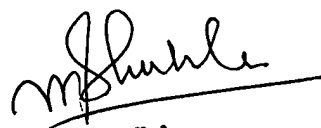
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is (703) 306-3221. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-8693 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

tcg
May 28, 2003


RAM SHUKLA
PRIMARY EXAMINER